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Citation

Chinelo Nsobundu, Yeka Nmadu, Nikita Sandeep Wagle, Margaret Foster, James Burdine, Marcia Ory, Lisako McKyer, Ledric Sherman. Process Evaluations of Traditional, Group-Based Diabetes Self-Management Education and Support Programs: A systematic review of the literature. PROSPERO 2020 CRD42020177170 Available from:

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Review question

The following research questions were formulated:

- 1) What is known from the existing literature about stand alone or embedded process, feasibility, and acceptability evaluations and/or assessments of traditional, group-based DSMES programs?
- 2) Based on existing literature, what process evaluation outcomes (characteristics) are included in traditional, group-based DSMES program studies? Process evaluation outcomes include fidelity (quality), dose delivered (completeness), dose received (exposure & satisfaction), reach (participation rate), recruitment, retention, and context (facilitators and barriers) as notated by Dr. Saunders' 2016 Implementation Monitoring and Process Evaluation textbook.
- 3) Based on existing literature, what methods have been used to conduct process, feasibility, and acceptability evaluations and/or assessments of DSMES programs?

Searches

To identify studies that met the inclusion criteria, the following bibliographic databases were first searched from inception until November 22nd, 2019.

Then, the search was later refined to include additional terms, and MEDLINE (Ovid) was searched until May 26th, 2020, while the following were searched until July 21st, 2020: Embase (Ovid), CINAHL (EBSCO), Academic Search, and PsycINFO.

The search strategy was developed by a Texas A&M University librarian specialized in conducting reviews. Then, the primary investigator searched and further refined the search.

The following search terms were used, alone or in combination: diabetes, self-care, self-management, lifestyle, process, implement, assess, evaluation, acceptability, and feasibility.

The electronic search was supplemented by searching for relevant studies and reviewing the grey literature.

Types of study to be included

Inclusion Criteria:

Quantitative (randomized, non-randomized, or quasi-experimental study), qualitative, or mixed-method research designs

Exclusion Criteria:

Review papers, commentaries/ letters to the editor, abstracts, poster board presentations, theses, dissertations, coursework papers, capstone papers, theoretical papers, protocols, cross-sectional studies

(i.e. secondary data analysis articles), article summaries of lessons-learned, cross-site/multi-site evaluations and assessments (which occur in multiple states and/or during different time periods) that do not provide information on the program or did not use the same diabetes-specific traditional, group-based self-management and/or lifestyle intervention.

Condition or domain being studied

Due to the multitude of associated complications, diabetes (DM) poses many threats to an individual's quality of life and requires a multi-faceted management approach. As part of this approach, Self-Management Education (SME) programs have been used to target those diagnosed with chronic conditions. These programs are imperative to assisting individuals in living the most optimal lives demonstrating improvements in health behaviors, health status, and healthcare utilization. Despite the wide range of Diabetes Self-Management Education and Support programs, there is minute evidence that addresses the process evaluation components of these programs, particularly traditional (face to face), group-based programs. The need to understand both program coverage and delivery via quantitative and qualitative process outcome measures is essential for the continued success of these programs and to determine the feasibility and acceptability of such programs.

Participants/population

Inclusion Criteria:

Studies possessing an inclusion criteria (in their methods section) of adults at least 18 years of age and older with either Type 1 or Type 2 Diabetes Mellitus.

Exclusion Criteria:

- Studies that possess an inclusion criteria of those below the age of 18 years of age with either Type 1 or Type 2 Diabetes Mellitus

Intervention(s), exposure(s)

Inclusion Criteria:

- Studies focusing on a diabetes-specific traditional, group-based self-management and/or lifestyle intervention (group medical visits, peer support groups, and hybrid models were included as long as it was diabetes-specific)

Exclusion Criteria:

-Studies including an additional chronic disease self-management intervention in combination with diabetes or studies that DO NOT focus on a diabetes-specific traditional, group-based self-management and/or lifestyle intervention

Comparator(s)/control

Control Group that is usual care, no treatment (non-exposed control group), waitlist controls will be included or a is a comparison intervention to a traditional, group-based DSMES program.

Context

Studies will not be excluded based on settings or locations. Studies to be included are English-Language written studies only.

Main outcome(s)

The study needs to be a stand-alone or embedded process, feasibility, and acceptability evaluations and/or assessments of a diabetes-specific traditional, group-based self-management and/or lifestyle intervention.

A minimum of 1 process evaluation outcome must be included.

Process Outcomes are listed and are categorized as follows:

1. Fidelity (Quality)

2. Dose Delivered (Completeness)
3. Dose Received (Exposure and/or satisfaction)
4. Reach (Participation Rate; those enrolled in the study divided by those eligible to participate (intended priority population, those that attended each class sessions, and/or documentation of barriers to attending a class session)
5. Recruitment
6. Retention (those who completed the program divided by those that enrolled)
7. Context (Facilitators and Barriers)

Measures of effect

Not applicable

Additional outcome(s)

None

Measures of effect

Not applicable

Data extraction (selection and coding)

A customized data extraction form for descriptive characteristics was developed and pilot tested by the

researchers. Descriptive data such as (1) study time and location, (2) participants and age group, (3) recruitment and sampling, (4) study design (includes control group), (5) diabetes self-management education intervention (i.e. type/name, frequency, and duration), (6) theoretical framework used to guide the process evaluation, if any (7) process outcomes such as fidelity (quality), reach, dose delivered (completeness), dose received (exposure & satisfaction), reach (attendance), recruitment, retention, and context (facilitators and barriers to program implementation), (8) critical appraisal score, (9) strengths of the study, (10) limitations of the study, and (11) implications for research and practice is currently being extracted.

The primary investigator will extract data from all included studies while the remaining two investigators will each extract half the number of all included studies. Authors of included studies will be contacted if additional information is needed to verify data extracted. Discrepancies will be resolved through discussions between the primary investigator and the remaining investigators.

Risk of bias (quality) assessment

The Mixed Method Appraisal tool will be used to assess the quality of each study. This tool assesses the

quality of five categories of studies such as qualitative research, randomized control trials, non-randomized studies, quantitative descriptive studies, and mixed-method studies. The MMAT tool will be embedded within the data extraction tool so that both the extraction and critical appraisal of an included study will occur simultaneously.

Strategy for data synthesis

Due to the diversity of studies, a narrative descriptive synthesis of findings will be performed structured

around the intervention characteristics, process evaluation outcome characteristics, methodology, findings, and quality. We are not using individual participant data. A meta-analysis will not be performed due to differences in study methodology, interventions, measures, and lack of feasibility.

Analysis of subgroups or subsets

None planned.

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Type and method of review

Intervention, Methodology, Narrative synthesis, Systematic review

Anticipated or actual start date

22 November 2019

Anticipated completion date

22 October 2020

Funding sources/sponsors

There are no funding sources/sponsors for this review.

Conflicts of interest

Language

English

Country

United States of America

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Diabetes Mellitus; Educational Status; Health Behavior; Humans; Process Assessment, Health Care; Self-Management

Date of registration in PROSPERO

05 July 2020

Date of first submission

31 March 2020

Stage of review at time of this submission

Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	No
Risk of bias (quality) assessment	Yes	No
Data analysis	No	No

Revision note

The following items were revised: 1. The eligibility criteria and PICO were updated2. Additional Review Team Members were added3. Status of Systematic Review was updated (Data Extraction & Critical Appraisal has been started)4. Updated Search Strategy was uploaded which was ran in 2020

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

05 July 2020

04 February 2021